

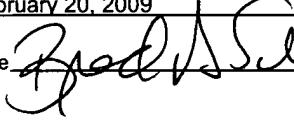
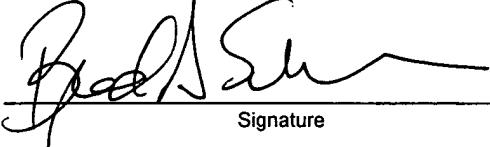
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)
		MSDI-214/PC365.06
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>February 20, 2009</u></p> <p>Signature </p> <p>Typed or printed name <u>Brad A. Schepers</u></p>		<p>Application Number</p> <p><u>10/645,413</u></p> <p>Filed</p> <p><u>August 21, 2003</u></p> <p>First Named Inventor</p> <p><u>Charles L Branch</u></p> <p>Art Unit</p> <p><u>3775</u></p> <p>Examiner</p> <p><u>James L. Swiger III</u></p>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).</p> <p>Note: No more than five (5) pages may be provided.</p>		
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. <u>45,431</u> Registration number _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>		<p> Signature</p> <p><u>Brad A. Schepers</u> Typed or printed name</p> <p><u>(317) 238-6334</u> Telephone number</p> <p><u>February 20, 2009</u> Date</p>
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>		

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent application of: ) Before the Examiner:  
Charles L. Branch et al. ) James L. Swiger III  
 )  
Application Serial No. 10/645,413 ) Group Art Unit 3775  
 )  
Filed: August 21, 2003 ) Ref. No. MSDI-214/  
 ) PC365.06  
 )  
INTERBODY FUSION GRAFTS ) February 20, 2009  
AND INSTRUMENTATION )

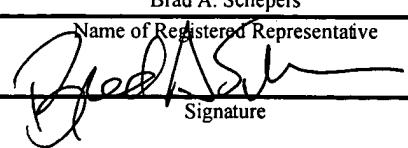
**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

**MAIL STOP AF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the final Office Action dated October 3, 2008 and the Advisory Action dated January 23, 2009, please consider the following. A Notice of Appeal and form PTO/SB/33 Pre-Appeal Brief Request for Review are submitted herewith along with the requisite appeal fee under 37 CFR 41.20(b)(1). Additionally, a request for a one-month extension of time including the requisite fee of \$130 is submitted herewith, thereby extending the time period for responding to the final Office Action and the Advisory Action to February 23, 2009 (i.e., one month from the mailing date of the Advisory Action). Please charge any additional fees which may be necessary to Deposit Account No. 12-2424, but not to include any payment of issue fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:
February 20, 2009
_____ Date of Deposit
Brad A. Schepers
_____ Name of Registered Representative
 _____ Signature
February 20, 2009
_____ Date of Signature

An Advisory Action mailed January 23, 2009 indicated that the previous response did not place Applicant's application in condition for allowance and was not entered. Each of the pending claims 51-55, 63-68, 70 and 73-85 stands rejected as being anticipated by U.S. Patent No. 5,928,139 to Koros et al. (hereafter "Koros"). As an initial matter, the body of the previous Office Action did not include an indication of finality or the requisite notice that the Office Action was made final under MPEP §706.07(a). (See pages 2-4). Accordingly, the Office Action should have been considered non-final. Furthermore, the entire basis regarding the anticipatory rejection of the pending claims is set forth in a single paragraph on page 2 of the Office Action.

As pointed out in Applicant's previous non-entered response, claims 84 and 85 (which were rewritten in independent form) recite features that are clearly not disclosed in Koros. Specifically, claims 84 and 85 each recite "wherein the retractor blade includes a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space, the distractor tip having a width corresponding to a distracted height of the intervertebral space and a rounded distal end transitioning to the width of the distractor tip" to facilitate the insertion into and the distraction of the intervertebral space", and "wherein the rounded distal end of the distractor tip defines a convex curvature transitioning to the width of the distractor tip". The Office Action generally asserts that Koros discloses that "[t]he device also has a distracter tip (60) to facilitate insertion". However, as discussed in detail below, this general allegation does not set forth sufficient grounds with the requisite specificity to establish a *prima facia* case of anticipation with regard to the above-listed features recited in claims 84 and 85.

As an initial matter, the distal end of the Koros blade 54 does not comprise "a distractor tip sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space", and likewise does not have "a width corresponding to a distracted height of the intervertebral space". Although the Office Action general alleges that "[t]he device also has a distracter tip 60 to facilitate insertion", the Office Action does not set forth any grounds whatsoever as to how Koros discloses these recited elements and features. Moreover, as shown in Fig. 5 of Koros, the distal end 60 of the blade 54 has a width that is significantly larger than the natural disc/space 98 between the adjacent vertebrae 94, 96, and is therefore clearly not "sized and shaped for insertion into an intervertebral space for distraction of the intervertebral space", nor does the distal end 60 have "a width corresponding to a distracted height of the intervertebral space". Furthermore, the distal end 60 does not have "a width . . . and a rounded distal end transitioning to the width of the distractor tip to facilitate the insertion into and the

distraction of the intervertebral space”, or that “the rounded distal end of the distractor tip defines a convex curvature transitioning to the width of the distractor tip”, as recited in claims 84 and 85. Indeed, as illustrated in Fig. 5 of Koros, the distal end 60 of the blade 54 defines a concave curvature extending across the width of the distal end 60, and does not include “a convex curvature” transitioning to the width of a distractor tip. Once more, the Office Action does not set forth any grounds or rational basis as to how Koros discloses that the distal end 60 of the blade 54 includes these recited elements and features. Indeed, the Office Action does not even mention the terms “rounded distal end”, “concave curvature” or “width”. Accordingly, a *prima facia* case of anticipation has clearly not established with regard to claims 84 and 85 via the general allegation that “[t]he device also has a distracter tip (60) to facilitate insertion.”

Furthermore, independent claim 51 recites a retractor body including “first and second enlarged edges . . . defining a channel therebetween” and “at least one supporting member mounted thereon for attaching a retractor pin, and a retractor pin attached to a first one of the at least one supporting member”, and a retractor blade received within the channel and nested between and engaged with the enlarged edges. With regard to Koros, even assuming arguendo that either of the upper support portions 44, 62 could be construed as a retractor body, and that the outer features 50, 52 and 68, 70 could be construed as “first and second enlarged edges . . . defining a channel therebetween” for receiving the lower blade portions 54, 64, the upper support portions 44, 62 do not include “at least one supporting member . . . for attaching a retractor pin, and a retractor pin attached to a first one of the at least one supporting member”. Instead, it is the lower blade portion 64 which includes the tubular guides 82 that have been construed as a “supporting member” for receiving the screws 83 (i.e., the elements construed as “a pin”). This configuration is contrary to the recitation in independent claim 51 that the retractor body includes the “at least one supporting member” and “a retractor pin attached to a first one of the at least one supporting member”. Indeed, the upper support portions 44, 62 of the Koros device (i.e., the elements construed as a retractor body) do not include any structure that could be construed as a “supporting member” for attachment of the screws 83. Instead, the screws 83 extend through the tubular guides 82 defined by the lower blade portion 64. (See Figs. 1, 3 and 6). Accordingly, Koros does not satisfy each of the elements and features recited in independent claim 51.

Independent claim 55 recites a retractor body including “first and second enlarged edges . . . defining a channel therebetween” and “a first supporting member and a second supporting member . . . positioned on opposite sides of the channel . . . and adapted for attaching a first and

a second retractor pin, respectively” with “the first retractor pin being attached to the first supporting member and the second retractor pin received for movement within the second supporting member”, and a retractor blade received within the channel and nested between and engaged with the enlarged edges. As indicated above, the upper support portions 44, 62 of the Koros device do not include structures that could be construed as supporting members with a first retractor pin “attached to the first supporting member” and a second retractor pin “received for movement within the second supporting member”. Instead, it is the lower blade portion 64 that includes the tubular guides 82 which have been construed as a “supporting member” for receiving the screws 83 (i.e., the elements construed as “a pin”). Indeed, the upper support portions 44, 62 do not include any structures that could be construed as first and second supporting members positioned on opposite sides of a channel for attachment to the screws 83.

Independent claim 73 recites a retractor body including “first and second support members defining a channel therebetween and each support member having an enlarged edge extending . . . along the channel” with “a first pin receivable within a first opening in the first support member and a second pin receivable within a second opening in the second support member”, and a retractor blade received within the channel and nested between and engaged with the enlarged edges. As indicated above, even assuming arguendo that either of the upper support portions 44, 62 of the Koros device could be construed as a retractor body defining a channel and an enlarged edge extending along the channel for receiving the blade portions 54, 64, the upper portions 44, 62 of the Koros device do not include “first and second support members” with “a first pin receivable within a first opening in the first support member and a second pin receivable within a second opening in the second support member”. Instead, it is the lower blade portion 64 including the tubular guides 82 which have been construed as “first and second support members” that define openings for receiving the screws 83. Indeed, the upper support portions 44, 62 of Koros do not include any structures that could be construed as first/second supporting members defining first/second openings which receive first/second pins.

Additionally, dependent claim 52 recites that “the at least one supporting member defines a hollow tube for receiving the retractor pin”. However, the upper support portions 44, 62 of the Koros device (i.e., the elements construed as “a retractor body” including at least one supporting member) do not include a hollow tube for receiving the screws 83. Although the lower blade portion 64 includes tubular guides 82 that could possibly be construed as a hollow tube for receiving the retractor pin, the upper support portions 44, 62 clearly do not define such features.

Furthermore, dependent claim 54 recites that “the retractor pin has a handle and a shaft disposed between the pin and the handle and slideably received in the at least one supporting member”, and dependent claim 74 similarly recites that “the second pin includes a handle and a shaft extending therefrom, the shaft comprising the second pin received in the second opening in the second support member”. However, the screws 83 of Koros (i.e., the elements construed as “a pin”) do not include “a handle”. Moreover, the Office Action does not set forth any grounds as to how Koros discloses a retractor pin having a handle. Although the Office Action refers to the boss 36 extending from the upper portion 44 of the Koros device as “a handle portion”, the boss 36 is not in any way associated with the screws 83. Additionally, dependent claims 82 and 83 recite a retractor pin that “includes external threads that are threadingly engaged with internal threads” defined by a corresponding supporting member. However, the screws 83 of Koros do not include external threads threadingly engaged with internal threads defined by the guides 82 of the blade portion 64 (i.e., the features construed as “supporting members”). Additionally, the Office Action does not set forth any grounds as to how the screws 83 of Koros are “threadingly engaged with internal threads” defined by a supporting member. Indeed, as shown in Fig. 5 of Koros, the screws 83 are not threadingly engaged with any portion of the retractor 10, but are instead threaded into the adjacent vertebrae 94, 96. Notably, the proximal elongate shank portions of the screws 83 are smooth and are non-threaded so as to freely slide within the tubular guides 82 of the blade 64. Also, dependent claim 80 recites that “the first and second support members . . . that receive the first and second pins also define the first and second enlarged edges of the retractor body”, and claims 67 and 68 similarly recite that “the first and second supporting members define the first and second enlarged edges of the retractor body engaged with the retractor blade”. However, the tubular guides 82 of the Koros device (i.e., the elements construed as “a supporting member”) which support the screws 83 do not also define the features 58 which have been construed as “first and second enlarged edges”.

In summary, many of the currently pending claims recite various features that are not disclosed by Koros, and the brief and summarial grounds of rejection set forth in the final Office Action fail to establish a *prima facie* case of anticipation with regard to these claims.

Respectfully submitted,

By:

  
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